

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Status of the claims**

Pending are claims 1, 2, 4-14, 16-21 and 24-29. Cancelled are claims 3, 15, 22 and 23. Amended are claims 1, 2, 4, 6-9, 11-14 and 17-20. The amendments merely clarify the claims and are supported by the original claims and specification, including at page 14, line 17 to page 15, line 8, and page 18, line 25 to page 19, line 8. New are claims 24-29 and recite subject matter removed by amendment from claims 9 or 20.

None of these amendments add new matter and are made to advance prosecution, without prejudice or disclaimer of subject matter removed by amendment. Applicant reserves the right to pursue cancelled subject matter in continuing applications with the same right of priority as the present application.

Withdrawn are claims 2, 3, 8-14, and 16-21, as allegedly corresponding to non-elected groups and/or species. New claims 24-29 depend from claims 9 or 20, which are withdrawn, and are therefore believed to be outside present consideration. Applicant respectfully requests rejoinder and examination of withdrawn claims upon the identification of allowable subject matter in claims 1 and 4-7.

Claims 1 and 4-7 are under examination.

**II. The withdrawal of claims 2 and 3.**

Claims 2 and 3 are withdrawn on the assertion that "claims 2 and 3 require the treatment of the sample with additional, or with a different combination of, compounds from the elected species." Office Action, page 2. Applicant respectfully disagrees with the reasoning of the Office as a basis for withdrawal of claims 2 and 3. The fact that a claim may *also* require additional elements is not a basis for its withdrawal from consideration, and the Office does not cite support for this practice. Following cancellation of claim 3, Applicant respectfully seeks rejoinder and examination of claim 2 and its dependent claims.

**III. Rejections under 35 U.S.C. § 112, second paragraph**

The rejection of claims 1 and 4-7 as allegedly indefinite is believed to be overcome by the foregoing amendments to the claims, which are as recommended by the Office.

**IV. Rejections under 35 U.S.C. § 102(b)**

At pages 4-5 of the Action, claims 1, 4 and 5 are rejected as allegedly anticipated by JP 11051940 to Aoyagi (Aoyagi I), and claims 1 and 4-6 are rejected as allegedly anticipated by WO 99/06836 to Aoyagi (Aoyagi II). Applicant respectfully traverses the rejection as it might have been applied to the pending claims.

As an initial matter, Applicant notes the relationship between Aoyagi I, Aoyagi II, and the present application. Aoyagi I and II share inventors with the present application, and are familiar to Applicant. JP 11051940 (Aoyagi I) is the publication of application JP 9/209515, upon which basis WO 99/06836 (Aoyagi II) was filed, and therefore is a closely related document. EP 0 967 484 (EP '484) is the English-language equivalent of WO 99/06836 (Aoyagi II). Applicant therefore believes that reference to EP '484 is proper for addressing the teaching of Aoyagi II and simplifies analysis of the issues at hand. Neither Aoyagi I nor II anticipates the pending claims.

Claim 1 recites a method of treating a sample suspected of containing hepatitis C virus (HCV) to release HCV antigen and to inactivate antibodies that bind to the HCV antigen, which method comprises treating the samples with a treating agent containing:

- (1) an acidifying agent,
- (2) an amphoteric surfactant or a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule,

wherein the method effects the release of the HCV antigen and the inactivation of antibodies that bind to the HCV antigen.

By contrast, EP '484 describes two *separate* compositions:

- (1) a combination of (a) an anionic surfactant, and (b) an amphoteric surfactant, nonionic surfactant or protein denaturant, and
- (2) a combination of (a) a chaotropic ion (i.e., protein denaturing agent) and (b) an acidifying

agent, as a pretreatment of sample so as to destroy HCV and liberating HCV antigen while simultaneously inactivating anti-HCV antibody in the sample. *See* abstract. Pages 23-26 of the US Application No. 09/269,897 (cited by the Office as equivalent to Aoyagi II, equivalent to pages 9-10 of EP '484) describes that a surfactant may be added to the combination of a chaotropic ion and an acidifying agent, but does not teach or suggest that an acidifying agent may be added to a surfactant without also the presence of a chaotropic agent. That is, EP '484 does not combine the use of an acidifying agent with an amphoteric surfactant or a cationic surfactant having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule.

EP '484 also does not recognize such a combination effects the release of the HCV antigen and the inactivation of antibodies that bind to the HCV antigen but, instead, requires the presence of, e.g., a chaotropic agent. Thus, EP '484 also does not enable the present claims.

Because EP '484 does not teach and enable the claims, it cannot anticipate. Applicant respectfully requests reconsideration and withdrawal of the rejection.

#### **V. Rejections under 35 U.S.C. § 103**

At pages 5-7 of the Action, claims 1 and 4-7 are rejected as allegedly obvious over the combination of WO 00/07023 to Aoyagi, as found in U.S. Patent No. 7,316,915 (Aoyagi III), in combination with Aoyagi II. Applicant respectfully traverses the rejection as it might have been applied to the pending claims.

Aoyagi III describes use of cationic surfactant or anionic surfactant, or a combination thereof, but does not teach or suggest a method that uses an acidic agent such as hydrochloric acid with an amphoteric surfactant or a cationic surfactant. Aoyagi II / EP'484, for reasons described above, but does not teach or suggest a method that uses an acidic agent such as hydrochloric acid with an amphoteric surfactant or a cationic surfactant. Because the combination of references does not teach or enable all elements of the claims, there is no *prima facie* obviousness.

The rejection also relies on an "obvious to try" rationale:

In view of the above, it would have been obvious to those of ordinary skill in the art to combine the steps of treating the samples with the acidifying agent and surfactants of Aoyagi II with the treatment of the samples with the detergents of Aoyagi for the purpose of reducing the number of agents required, and the number of steps being used to treat the samples.

Action at page 6. The courts have repeatedly held that obvious to try does not constitute obviousness when the only motivation relates to general research in an unpredictable field. For example, in *In re Kubin* 561 F.3d 1351 (Fed. Cir. 2009), the court identified that an impermissible “obvious to try” situation occurs where “*what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation*, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *Kubin* 561 F.3d at 1359 (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)) (emphasis added). The alleged motivation to practice the method with the claimed treating agent falls squarely within the example identified by *Kubin* as **not** supporting obviousness. Accordingly, the present rejection must fall as lacking any proper legal foundation.

The invention is also not obvious because it exhibits unexpected results over the prior art. Objective criteria of nonobviousness, such as unexpected results “is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness” that must be given full consideration. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir., 2008). In view of the unexpected results, the obviousness rejections are improper and should be withdrawn.

In particular, EP ‘484, in paragraph [0091], describes as a surfactant suitable for exposure of virus antigen, “In the above surfactant having an alkyl radical and a secondary, tertiary or quaternary amine, the alkyl group is preferably a straight-chain alkyl group and the number of carbon atoms therein is preferably 10 or greater, and more preferably 10 to 20.” However, these surfactants are used only in Example 15 “Method for effective detection without pretreatment of the antigen.” This assay method in EP ‘484 does not require “the inactivation of antibodies that bind to the HCV antigen.” On the other hand, the present invention destroys the HCV, liberates HCV antigen, and inactivates anti-HCV antibodies that

bind to the HCV antigen by using a combination of (a) an acidic agent (hydrochloric acid) and (b) an amphoteric surfactant (N-tetradecyl-N,N-dimethyl-3ammonio- 1-propanesulfonate) or a cationic surfactant (decyltrimethylammonium bromide) having both a straight chain alkyl group of 10 or more carbon atoms and a tertiary amine or a quaternary ammonium salt in the same molecule.” Thus, the present method effects a beneficial result with a simpler composition.

Table 13 in Example 8 of the present invention shows that the a very low titer of HCV antigen could be detected following the use only of surfactant, urea and reducing agent, while the use of an acidifying agent greatly increases the titer of HCV antigen detected from the same sample. The unexpected and surprising benefit provided by acidification is not described or suggested in the prior art.

Moreover, as can be seen from Example, page 23, line 30 to page 24, line 37, and Table 3, of the present application, the amphoteric surfactants recited in claims 6 and 7 show a very high effect in increasing the titer of HCV antigen detected in a sample. The unexpected benefits of these specific surfactants is not taught or suggested by the prior art.

Because the prior art alone or in combination, does not teach or suggest the present claims, nor their unexpected results, Applicant believes that the claims are nonobvious. Applicant therefore respectfully requests reconsideration and withdrawal of the rejection.

**CONCLUSION**

Applicant believes that the elected claims are in condition for allowance, and respectfully request favorable reconsideration and withdrawal of the rejections, and rejoinder, examination, and allowance of the non-elected claims.

Examiner Lucas is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution.

The Commissioner is authorized to credit any overpayment, or charge any additional fees which may be required under 37 C.F.R. §§ 1.16-1.17, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, because of incorrect or absent credit card payment via EFS-Web, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to the Deposit Account. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to the Deposit Account.

Respectfully submitted,

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